# Policy and Procedures for Research Ethics

Institute for Optimum Nutrition

## 1. Guiding Principles in Summary

1.1 ION is committed to the five commitments outlined in the Concordat to Support Research Integrity (2019 Revision); and the principles contained within the ION Code of Practice Governing the Ethical Conduct of Research which promotes good practice and preventing misconduct.

1.2 ION is guided by the fundamental principle that research involving humans should involve no more than minimal risk to physical or psychological well-being.

1.3 ION is concerned to protect the rights, dignity, health, safety, and privacy of research participants, including researchers and the integrity of the environment. ION is also concerned to protect the health, safety, rights and academic freedom of researchers and its reputation as a centre for properly conducted, quality research.
*Universities UK (2019) Concordat to Support Research Integrity.*

1.4 ION is responsible for ensuring that its research is carried out in conformity with current legislation. Relevant Data Protection legislation and ION guidance in data security must be observed in the collection, use, storage, back-up and eventual destruction of all data.

1.5 ION is an educational charity and is guided by charity law. ION will only use its funds for research that falls within its charitable objectives. Additionally, charity law imposes certain obligations and restrictions on the use of charitable funds for research, for example a requirement to disseminate research findings, and a proscription on funding research for the purpose of commercial or private gain.

1.6 ION provides induction and ongoing staff development (supervision, mentoring and training) for all staff and members of the Research Ethics Committee on research integrity.

1.7 ION also expects its researchers, research module leaders and supervisors, and REC committee members to be familiar with their obligations in relation to the relevant external bodies and to ensure that their work complies with these guidelines and expectations, regardless of the source of funding (see Reference List).

1.8 ION is committed to Open Access (OA) publishing. Peer-reviewed research will be made freely available online, with as few restrictions on how the works may be re-used as possible.

# 2. Classification of Research

2.1 Research may be defined as "a process of investigation leading to new insights, effectively shared. It includes work of direct relevance to the needs of commerce, industry, and to the public and voluntary sectors; scholarship; the invention and generation of ideas, images, performances, artefacts including design, where these lead to new or substantially improved insights; and the use of existing knowledge in experimental development to produce new or substantially improved materials, devices, products, and processes, including design and construction." *Universities UK (2012) Concordat to Support Research Integrity.*

# 3. Operating Procedures

3.1 The ION Research Ethics Committee's (REC) primary focus is to consider general ethical issues concerning activities of research undertaken by staff and students or other individuals working with ION, in accordance with the Code of Practice Governing the Ethical Conduct of Research (The Code).

3.2 The REC is also responsible for an ethical approval system for research including a generic approval system for Class 1 applications.

3.3 The REC is also responsible for upholding ION's position on avoidance of the use of animals in research.

3.4 In addition to considering submissions for approval the REC has several monitoring, reviewing, and reporting duties e.g. provide reports on ethics approval activities, staff development needs, serious events, and misconduct to the Education Committee (Trustees), keep under review the Code of Practice Governing the Ethical Conduct of Research, with regard to external developments. See the Research Committee Terms of Reference for full list of responsibilities. A record (monitoring and review grid) will be kept and reviewed at each meeting. Progress is reported to the Education Committee.

3.5 The Education Committee has oversight of the provision, institutionally, of ethics guidance, development, and training for staff.

3.6 The REC reports to the Education Committee and to external bodies on research integrity, through the Annual Monitoring Report* using the Five key themes of the Concordat (2019):

1. Policies and systems
2. Dissemination
3. Culture and development
4. Addressing research misconduct
5. Monitoring and reporting

3.7 *UK Research Integrity Office (UKRIO) Self-Assessment Tool for The Concordat to Support Research Integrity V2 (2021)

3.8 For purposes of ethical approval, the following classes of research have been established

*Class 1:*

Work which after due consideration (assessment outcome moderation) by the project module coordinator / principal investigator has been found to have no or minimal ethical implications. The module coordinator through the process of assessment and moderation is responsible for the ethics approval classification of taught UG and PG research and for ensuring that the students being supervised comply with the requirements of The Code and any other relevant codes and professional guidelines, both internal and external.

Supervisors must inform the module coordinator if there is a title change or if they observe the student may transgress the Class 1 boundaries.

The REC must monitor and report on the local processing of Part A Application Forms to the Education Committee.

*Class 2:*

Work which has clear ethical implications, and which may cause, or has the potential to cause, harm in any form to participants, investigator or to the environment.
The REC receives Part A and Part B of the Ethics Application Form.

**Must have institutional approval and Part A and Part B of the Ethics Application Form:**

*Class 3a:*

Work for which the approval of an external ethics body is required.

*Class 3b:*

Work which due to external requirements e.g. those of funders requires institutional confirmation of ethics consideration and/or approval through the REC.

*Class 4:*

Work which has significant ethical implications or the potential to cause a significant risk of harm, including research where there may be an institutional/reputational risk.

The Research Ethics Committee may approve applications for generic approval e.g. undergraduate research projects taking place in the Optimum Nutrition Training Clinic.

# 4. Research Ethics Committee

*Quorum*

4.1 A quorum of the Research Ethics Committee shall comprise a minimum of 40% of the members, including the Chair or their nominee and excluding the administrator. The REC should not normally consider applications unless at least 40% of the Committee are able to consider the

applications, excluding the administrator. However, provision may be made to approve applications by Chair's Action or through a smaller panel where business cannot be postponed until the next calendared meeting. In this case, Chair's Action or panel consideration and decisions should be recorded and reported at the next opportunity to the REC.

## *Conflict of Interest*

4.2 Applications to the ethics committee are circulated in advance of the meeting allowing conflict of interest by members to be declared in advance of the Committee meeting. Members with a conflict of interest will not be able to contribute to the processing or outcome of the identified application but may be able to remain present or participate in a discussion if invited by the Committee. Conflicts of interest will be recorded in the minutes.

## *Decisions:*

4.3 The Committee shall consider each Application for Ethics Approval, and the decision of the Committee shall be either:

- to approve the application
- to approve the application subject to conditions or modifications
- not to approve the application but invite the applicant to resubmit a revised or new application after addressing the concerns/conditions of the committee
- not to approve the application

4.4 The Committee will refer Applications for Ethics Approval for external consideration and/or approval as necessary.

4.5 The applicant shall be notified by the administrator of the Committee's decision via email within seven working days of the meeting at which the application was considered.

4.6 Relevant legislation and professional guidance should be applied to all research work as well as the Code of Practice Governing the Ethical Conduct of Research.

## *Full Approval*

4.7 Approval shall normally be for the duration of the research project which should be stated in the application form.

## *Approval Subject to Conditions or Modifications*

4.8 An application which has been approved subject to conditions and/or modifications should be resubmitted by the applicant, and supervisor where relevant with revisions as required to the Committee Administrator within 10 working days of the date of the notification email.

4.9 Approval shall normally be for the duration of the research project which should be stated in the application form.

4.10 Research should not normally begin until such modifications have been provided and approved by the Committee or separately by Chair's action.

4.11 The Committee may require as part of the Application for Approval, either written confirmation that the Institute's Insurers are content for their policy to apply, or that appropriate additional insurance cover needs been arranged.

4.12 The Committee may require that changes are made to a research protocol for health, safety and wellbeing reasons.

*Not to Approve the Application (with or without an invitation to submit a revised or new application)*

4.13 The Committee may request the researcher, and supervisor where relevant to submit a new application, with or without advice to the applicant. The new application will receive a new Ethics Application Number and will be considered by the Committee at another meeting.

4.14 The Committee may refuse to accept a revised application.
     If a proposal has been rejected and new information becomes available, a revised application may be submitted.

# 5. Appeals

5.1 An appeal against a decision by the Research Ethics Committee may be made to the Education Committee only on the grounds that there has been demonstrable material irregularity in the conduct of the Committee's procedures. The decision of the Education Committee will be final.

5.2 The appeal must be submitted to the Education Committee no later than 10 working days after the receipt of the Research Ethics Committee's decision.

5.3 The conclusion of an appeal may determine:

- That the appeal is upheld and refer it back to the Research Ethics Committee for review; or
- That the original decision of the Research Ethics Committee is upheld and that no further action be taken.

5.4 The result of an appeal will be notified in writing to the appellant within 10 working days of the decision being reached.

5.5 A yearly record of appeals will be submitted, as part of the REC Annual Report, to the Education Committee.

# 6. Chair's Action

6.1 In exceptional cases, Chair's Action can be applied in between scheduled meetings, but the use of this will be avoided where a decision by the Committee can be made by an electronic meeting or correspondence instead. Where Chair's Action has taken place, it will be reported and ratified at the next scheduled meeting.

6.2 Where the Committee has set conditions, and it agrees that these conditions can be reviewed and considered as having been met by the Chair, this can occur outside of scheduled meetings.

6.3 The Chair, along with a member of the Education Committee, will also be responsible for regulating access to students as research participants from both internal and external applicants. This is to protect students from external surveys that have not received ethical approval from a relevant body and avoid over-burdening them with participation requests.

6.4 The Chair along with a member of the Education Committee must meet to approve permission to proceed for Stage 3 and Stage 4 applications.

6.5 Where it is not clear which class proposed undergraduate research falls into, advice should be sought from the Chair. If it is not clear whether the research falls under Class 1, it should be forwarded to Research Ethics Committee for review.

# 7. Procedure

7.1 ION aims to promote good academic practice in research by asking individual researchers to complete and retain an initial assessment document (Ethics Application Form Part A), to demonstrate that ethical implications have been considered. Where there are ethical implications, an Ethics Approval Form Part B must be completed and submitted to the Research Ethics Committee.

1. All applications for research ethics approval to the Research Ethics Committee should be submitted using the research ethics approval application forms.
2. Applications must be complete, dated and signed and prepared in accordance with the format provided.
3. Applications from students must be checked and signed by the Research Project module coordinator.
4. Staff applications must be signed by the relevant line manager.
5. Ethical approval shall be obtained before the commencement of any research which has ethical implications. The Research Ethics Committee may allow part of the research to commence, prior to full approval being granted for those aspects of the research which do not relate to the ethical implications, but which are intended to contribute to the final piece of research.
6. The Research Ethics Committee reserves the right to request modifications or clarifications of any applications/proposals.
7. A Principal Investigator or researcher cannot attend any discussion involving their own research proposal even if they are members of the Committee (except by invitation).
8. Members must declare any special interest including personal, departmental, or financial etc.
9. If the Chair is involved in any such conflict of interest(s) then the vice-chair or nominee from the Education Committee will take over until the discussion is concluded.
10. The Research Ethics Committee will seek expert guidance or advice as required through the co-opting of additional membership.
11. Applications for Research Ethics Committee approval should reach the Administrator no later than seven working days before the meeting at which they are to be considered.
12. Committee meeting dates are published in advance of the Academic Calendar and Module Handbooks.
13. The REC will maintain a register of all current projects involving students to enable a full overview of research activity.
14. The REC will report serious events to the Education Committee.

15. The REC will Report suspected incidents of Research Misconduct to the Education Committee.

# 8. Research Misconduct

8.1 ION, through the Education Committee, treats all reported allegations of Research Misconduct seriously, requires that they are investigated fully and that the outcomes are reported to the appropriate Regulatory Bodies, Partners and the Education Committee.

8.2 Investigations of alleged Research Misconduct should be carried out thoroughly, sensitively, in a timely manner and under a presumption of innocence. The Respondent will be given an opportunity to respond before any decision is made.

8.3 Should the Respondent leave ION, the allegation may still be investigated as far as possible and appropriate recommendations/actions proposed and implemented.

8.4 Researchers, Supervisors or Students attempting to influence, victimise or intimidate an Initiator of an allegation of misconduct, or a witness will themselves be subject to disciplinary action (gross misconduct). Similarly, any organisation condoning such behaviour may also be subject to action by ION.

8.5 ION requires that instances of potential Research Misconduct should be reported (see Code of Practice Governing the Ethical Conduct of Research). ION will assume that an allegation is made in good faith and that it is the Initiator's belief that misconduct may have occurred. As such, ION will aim to provide appropriate support for the Initiator. Equally, ION is committed to protecting Researchers from frivolous, vexatious, or malicious accusations. Where it is found that an Initiator has acted in bad faith, which includes raising frivolous, vexatious, or malicious allegations, this will be treated as a serious matter and may lead to disciplinary action.

8.6 All parties involved in the management of an allegation of potential Research Misconduct are required to maintain confidentiality in so far as it is practicable. Where it is considered, it may be necessary to disclose confidential information, a balance will be drawn between preserving confidentiality and the need for informed discussion.

# 9. Examples of Research Misconduct

9.1 The ION Code of Practice Governing the Ethical Conduct of Research sets out the ION's position regarding research integrity and good practice and its expectations that all parties involved in research activities will exhibit the highest standards of research integrity and conduct. A failure to observe these standards may result in an allegation of Research Misconduct.

9.2 The following are examples of Research Misconduct that may be investigated using this procedure (this list is non-exclusive and non-exhaustive):

- Fabrication
- Falsification
- Misrepresentation of data and/or interests and/or involvement
- Plagiarism (including the inappropriate use of generative AI (GAI)

- Inappropriate attribution of authorisation
- Inciting others to be involved in Research Misconduct
- Collusion in or concealment of Research Misconduct of others
- Failure to obtain appropriate permission to conduct research
- Failure to declare an interest in the commission, completion or outcome of research activities
- Failures to follow accepted procedures or to exercise due care in carrying out responsibilities for avoiding unreasonable risk or harm to humans and or the environment
- Breach of a duty of care, including:
  - Breach of confidentiality without consent
  - The improper handling of privileged or private information on individuals collected during the research. (e.g. data protection or Information Security)
  - Placing parties either directly or indirectly associated with the research in danger without valid consent and appropriate safeguards being in place
  - Failing to observe legal and ethical requirements
  - Improper peer review of proposals, results, or research outputs

9.3 For the avoidance of doubt, a Researcher may be subject to an allegation of misconduct in research for:

- Acts of omission as well as acts of commission, and
- Failing to report an act of Research Misconduct.

# Bibliography

ION Code of Practice Governing the Ethical Conduct of Research 2018/19

Ethics Application Form Part A and Part B

Student Research Misconduct Regulations see Student Code of Conduct, Regulations Handbook

Staff Research Misconduct Procedure

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